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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/763,836	06/08/2001	Osamu Yamada	19036/37156	3756

7590

08/23/2004

Thomas A Cawley Jr  
Marshall O'Toole Gerstein Murray & Borun  
6300 Sears Tower  
233 South Wacker Drive  
Chicago, IL 60606-6402

EXAMINER
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SULLIVAN, DANIEL M

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 08/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

9/11

## Office Action Summary

**Application No.**

09/763,836

**Applicant(s)**

YAMADA ET AL.

**Examiner**

Daniel M Sullivan

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 06 May 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 21-23, 26, 28-31, 33-39, 44, 45, 49-53, 55 and 56 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 21-23, 26, 28-31, 33-39, 44, 49-53, 55 and 56 is/are allowed.
- 6) ☒ Claim(s) 45 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### **DETAILED ACTION**

This Office Action is a reply to the Paper filed 6 May 2004 in reply to the Non-Final Office Action mailed 6 February 2004. Claims 21-24, 26, 28-31, 33-39, 44, 45 and 47-65 were considered in the 6 February Office Action. Claims 24, 47, 48, 54 and 57-65 were canceled and claims 21-23, 28, 30, 35, 36, 38, 39, 45, 51, 52, 55 and 56 were amended in the 6 May Paper. Claims 21-23, 26, 28-31, 33-39, 44, 45, 49-53, 55 and 56 are presently pending and under consideration.

### ***Response to Amendment***

Rejection of and objection to claims 24, 47, 48, 54 and 57-65 is rendered moot by the cancellation thereof.

### **Claim Rejections - 35 USC § 112**

Rejection of claims 21-23, 28-31, 35, 36, 38, 39, 44, 49-53, 55 and 56 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn.

Claim 45 stands rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

In the remarks filed with the 6 May Paper, Applicant urges that the claim now meets the written description requirement because the phrase "fragments thereof that includes said thymidine" has been deleted.

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However, claim 45 still encompasses the polynucleotide set forth as SEQ ID NO: 7 over its entire length wherein the polynucleotide has a substitution, deletion, insertion and/or addition of a single or a few nucleotides taken from a gene of a wild type virus within the sequence or proximate sequence in at least one position corresponding to a pyrimidine-rich tract, BoxA, BoxB an/or transfactor-binding site. There is no limitation on where mutations are comprised within the nucleic acid (other than a minimal requirement that at least one mutation be comprised within a pyrimidine-rich tract, BoxA, BoxB an/or transfactor-binding site), there is no limitation on the degree to which the mutant sequence can vary relative to SEQ ID NO: 7 and there is no limitation on how many substitutions, deletions, insertions and/or additions of a single or a few nucleotides might be comprised within a single nucleic acid. For example, the nucleic acid of the claim might be identical to SEQ ID NO: 7 except for a single base substitution, or it might comprise multiple substitutions, deletions, insertions and additions of a single or a few nucleotides relative to SEQ ID NO: 7 and therefore be only distantly related to the sequence disclosed as SEQ ID NO: 7. For reasons of record, the latter nucleic acids fail to meet the written description requirement of 35 U.S.C. §112, first paragraph. Therefore, claim 45 stands rejected.

#### Claim Rejections - 35 USC § 102

Rejection of claims 21, 22, 28, 29, 31, 35, 44, 49, and 51-53 under 35 U.S.C. 102(b) as being anticipated by Yoo *et al.* (1992) *Virology* 191:889-899 as evidenced by Brown *et al.* (1992) *Nucleic Acids Res.* 20:5041-5045 is withdrawn.

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Rejection of claims 21-23, 28-31, 35, 36, 44, 49, 50, 53, 55 and 56 under 35 U.S.C. 102(b) as being anticipated by Collier *et al.* (1998) *J. Gen. Virol.* 79:2359-2366 is withdrawn.

Claim 45 stands rejected under 35 U.S.C. 102(b) as being anticipated by either one of Yoo *et al.* (*supra*) or Collier *et al.* (*supra*).

Amended claim 45 is directed to a polynucleotide for enhancing protein expression, which comprises the polynucleotide set out in SEQ ID NO: 7 over its entire length and has a substitution, deletion, insertion and/or addition of a single or a few nucleotides taken from a gene of a wild type virus within the sequence or proximate sequence in at least one position corresponding to a pyrimidine-rich tract, BoxA, BoxB an/or transfactor-binding site.

In the remarks filed with the 6 May Paper, Applicant alleges that claim 45 is directed to a polynucleotide comprising the nucleotide sequence set out in SEQ ID NO: 7 over its entire length. However, the phrase “within the sequence” is construed as including the sequence set out in SEQ ID NO: 7 and including the thymidine insertion at the position corresponding to between position 206 and 207 of SEQ ID NO: 1, which distinguishes SEQ ID NO: 7 from the art. Therefore, the claimed nucleic acid encompasses a nucleic acid comprising the sequence set forth as SEQ ID NO: 7 wherein the thymidine insertion at the position corresponding to between nucleotide 206 and 207 of SEQ ID NO: 1 has been deleted.

As described in previous Office Actions, Yoo *et al.* teaches an expression vector comprising a nucleic acid sequence of the 5' UTR of hepatitis C virus (page 890, left

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column, bottom paragraph and page 891, right column, bottom paragraph) enhancement the expression of CAT protein *in vitro* and in cultured mammalian cells (page 892, left column, lines 1-2). In particular, Yoo *et al.* teaches that the nucleotides 1-341 of the 5' UTR were introduced into a vector (page 891, right column, bottom paragraph) and several deletion constructs (see especially Figure 1C and the caption thereto) were used in studying the expression-enhancing ability of the HCV 5' UTR. Collier *et al.* teaches a novel bicistronic dual luciferase reporter construct assay system for studying translational efficiencies of 5' UTR from hepatitis C virus, wherein the translation of firefly luciferase is directed by HCV 5' UTR as an IRES (see especially Figure 2, page 2362 and Figure 3, page 2364) *in vivo* and *in vitro*. These constructs meet all of the limitations of various mutants falling within the scope of claim 45. Therefore, the claim stands rejected under 35 U.S.C. §102(b) as anticipated by the prior art.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the

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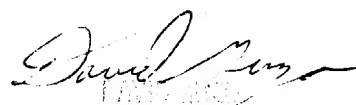
advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 571-272-0779. The examiner can normally be reached on Monday through Thursday 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Daniel M Sullivan, Ph.D.  
Examiner  
Art Unit 1636



PRIMARY EXAMINER